

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q76592

Masahiro OKUDA

Appln. No.: 10/622,736

Group Art Unit: 1651

Confirmation No.: 2795

Examiner: Susan Marie Hanley

Filed: July 21, 2003

For: REAGENT KIT FOR DETECTING LUPUS ANTICOAGULANT

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The required copies of the listed documents have been provided in co-pending Application Nos. 11/050,766 or No. 10/811,385, and therefore are not being re-submitted. The listed documents were cited as references of record in co-pending U.S. Application Nos. 11/050,766 or 10/811,385; references that were cited in U.S. Application Nos. 11/050,766 or 10/811,385, but which have already been cited in the present application, are not re-listed herein.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


Respectfully submitted,

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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

  
Joseph J. Ruch, Jr.  
Registration No. 26,577

Date: June 18, 2007

Substitute for Form 1449 A & B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	10/622,736
				Confirmation Number	2795
				Filing Date	July 21, 2003
				First Named Inventor	Masahiro OKUDA
				Art Unit	1651
				Examiner Name	Susan Marie Hanley
Sheet	1	of	2	Attorney Docket Number	Q76592

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US-5,705,198		01-06-1998	Triplett et al.
		US-6,777,193		08-17-2004	Baeza-Ramirez et al.
		US-2003/0232075		12-08-2003	Nelsestuen, Gary L.
		US-2004/0091952		05-13-2004	Okuda
		US-2004/0197837		10-07-2004	Okuda et al.
		US-2007/0026467		02-01-2007	Greenfield et al.
		US-6,261,792	B1	07-17-2001	Janoff et al.
		US-5,834,223		11-10-1998	Griffin et al.
		US-4,914,040		04-03-1990	Lenz et al.

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		EP	1 385 003	A1	01-28-2004	SYSMEX CORP	
		JP	2004109034		04-08-2004	Kato et al.	
		JP	5180835	A	07-23-1993	SRL KK	Complete
		WO	01/21183	A1	03-29-2001	The Liposome Co., Inc.	

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Astumi et al. (abstract) Igaku to Yakugaku, vol. 45(1), 2001, pages 123-127.	
		SCHJETLEIN, R. et al., "A Quantitative, Semi-Automated and Computer-Assisted Test for Lupus Anticoagulant," Thrombosis Research 69, 1993, pages 239-250.	
		SAKAKURA et al., Coagulation Tests And Anti-Phospholipid Antibodies In Patients Positive For Lupus Anticoagulant, CLINICAL AND APPLIED THROMBOSIS/HEMOSTASIS: OFFICIAL JOURNAL OF THE INTERNATIONAL ACADEMY OF CLINICAL AND APPLIED THROMBOSIS/HEMOSTASIS, July 2000, pages 144-150, Vol. 6 - No. 3.	
		NORBIS FRANCESCA et al., Diluted Russell's Viper Venom Time And Colloidal Silica Clotting Time For The Identification Of The Phospholipid-Dependent Inhibitors Of Coagulation, THROMBOSIS RESEARCH, 1997, pages 427-431, Vol. 85 - No. 5.	
		SIBILIA JEAN, Antiphospholipid Syndrome: Why And How Should We Make The Diagnosis?, JOINT, BONE, SPINE: REVUE DU RHUMATISME, March 2003, pages 97-102, Vol. 70 - No. 2.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Number	Kind Code <sup>2</sup> (if known)		
		US-4,281,061		07-28-1981	Zuk et al.
		US			
		US			
		US			
		US			
		US			
		US			
		US			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
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NON PATENT LITERATURE DOCUMENTS			
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		Arthritis & Rheumatism 2000; 43(9):1982-93	
		Thrombosis and Haemostasis 1995; 74(4):1185-90	
		Arthritis & Rheumatism 1999; 42 (7):1309-11	
		Guidebook on Laboratory Tests, published 1998; Kanehara & CO., LTD 31st edition: pages 442- 443	Yes
		Galli et al. Blood, vol. 93(7): 2149-2157, 1999	

Examiner Signature		Date Considered	
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